K121637

OCT 25 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 4, 2012

Company and Correspondent making the submission:

Name – Sunwell Biotech Co., Ltd.
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Contact – Mr. Charlie Mack
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Device :

Trade/proprietary name: Auto–Disable Sterile Safety Syringe For Single Use, 5mL

Common Name : Antistick Syringe

Classification Name : Piston, Syringe

Predicate Device:

Model	Manufacturer	K Number	Submitted Device
Invirosnap Safety Syringe, 1ml 2ml 3ml 5ml 10ml and 20ml	Inviro Medical Devices, Inc.	K092430	Auto–Disable Sterile Safety Syringe for Single Use, 5mL

Classifications Names & Citations :

21CFR 880.5860, MEG, Anti-Stick Syringe, Class II

Description :

General

The Auto–Disable Sterile Safety Syringe for Single Use is used to inject fluids into, or withdraw fluids from the body. In addition, the retractable needle of the syringe goes into the barrel after use. It is designed to aid in the prevention of needle stick injuries.

The retractable type of piston syringe is a plastic disposable anti-needle stick syringe made of the below components:

1. Cap – Covers the needle until the syringe is to be used
2. Needle – The needle penetrates the patient's skin to inject/withdraw fluid from the body
3. Needle house – a plastic part, as a assembly part with needle to fasten together with epoxy glues
4. Hub – a plastic part for minimizes the risk of leakage around the needle assembly
5. Barrel – The barrel has a scale showing the capacity of the syringe , in addition ,the top of the barrel has a airproof ring lock fitting for minimize risk of leakage around the Hub
6. Gasket – A TPE (Thermoplastic Elastomer) molding part. The gasket is to be assembled with plunger for bring plus/minus pressure within barrel when the plunger to be fully depressed/retracted
7. Plunger – Once the plunger is fully depressed, it engages the needle assembly, as the plunger is retracted ,the needle assembly is retracted into the barrel, once the plunger is fully retracted and locked in place, the plunger is snapped off leaving the needle in the barrel of the syringe

Indications For Use

The Auto–Disable Sterile Safety Syringe for Single Use ,5ml, is used to inject fluids into, or withdraw fluids from the body. In addition, the retractable needle of the syringe goes into the barrel after use. It is designed to aid in the prevention of needle stick injuries.

Sterilization:

Sunwell Biotech Co., Ltd., has successfully performed the EO validation according to ISO 11135-1:2007 for Auto–Disable Sterile Safety Syringe for Single Use. All predetermined parameters have been met.

Biocompatibility:

The biocompatibility study has been conducted for Auto–Disable Sterile Safety Syringe for Single Use 5ml according to the below applicable standards:

In Vitro Cytotoxicity (ISO 10993-5:2009)

Delayed Contact Sensitization Study in the Guinea Pig (ISO10993-10:2010)

Intracutaneous Test (ISO10993-10:2010)

Systemic Toxicity (Acute) (ISO10993-11:2006)

Hemolysis Test (ISO 10993-4-2002/Amd. 1:2006)

Complement Activity Test (ISO 10993-4-2002/Amd. 1:2006)

Thrombosis Test (ISO 10993-4-2002/Amd. 1:2006)

Package and Shelf Life:

Testing was performed to demonstrate package and shelf life verification. The study shows that the subject sterilization package complies with the applicable standards and support the 3 years shelf life claim. The tests noted below were performed:

Accelerated Aging of Sterile Barrier Systems (ASTM F1980-07)

Sterilization of medical devices - Microbiological methods (AAMI/ANSI/ISO 11737-2:2009 - Part 2)

Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission (ASTM D3078-02)

Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (ASTM F1929-98)

Test Method for Seal Strength of Flexible Barrier Materials (ASTM F88/F88M-09)

for terminally sterilized medical devices - Part 1: (AAMI/ANSI/ISO 11607-1:2006/)

Sterile hypodermic syringes for single use - Part 1: (ISO 7886-1:1993)

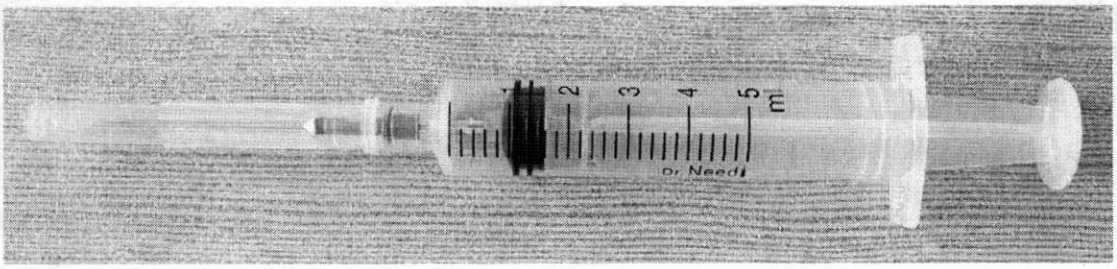
Sterile hypodermic needles for single use (ISO 7864 Third edition 1993-05-15)

Stainless steel needle tubing for the manufacture of medical devices (ISO 9626 First edition 1991-09-01, AMENDMENT 1 2001-06-01)

Simulated Clinical Use Study

Sunwell Biotech Co., Ltd conducted simulated clinical use study of Auto–Disable Sterile Safety Syringe for Single Use, 5ml, in accordance with the FDA Guidance for industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features, August 9, 2005. The objective was to assess the reliability and usability of the safety feature of that device. Based on the simulated clinical use test recommended in that document, 10 nurses were recruited. They tested a total of 500 Auto–Disable Sterile Safety Syringe for Single Use and 100 samples of a similar products, the Invirosnap Safety Syringe(Which is already marketed in the United States with K092430), and reported their experience with each sample. The safety mechanisms and the user actions of the two devices are similar. Samples of the both syringes were provided by Sunwell Biotech Co., Ltd.

Product Picture



Comparison with predicate device :- Please see the next page

SE Table

Element of comparison	Subject Device	Claimed SE Device
Company	Sunwell Biotech Co., Ltd.	Inviro Medical Devices, Inc.
FDA510(K) Number	N/A	K092430
Device Name	Auto–Disable Sterile Safety Syringe for Single Use	Invirosnap Safety Syringe
Model Number	5ml	1ml 2ml 3ml 5ml 10ml and 20ml
Intended Use	The Auto–Disable Sterile Safety Syringe for Single Use is used to inject fluids into, or withdraw fluids from the body. In addition, the retractable needle of the syringe goes into the barrel after use. It is designed to aid in the prevention of needle stick injuries	The InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.
Principle of operation	Identical	After use, the health care professional fully depresses the plunger to engage the luer assembly. Once the luer assembly is engaged, pulling back the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a sharps container.
Safety feature	Identical	Manually retractable safety syringe with permanent disable
Specific drug use	Identical	Conventional drugs
Sterilization	Identical	Sterilized by ethylene oxide gas
Needle length	Identical	1 1/4 Inch
Needle gauge	22G	21/22/23G
Needle tip configuration	Identical	Tri-Beveled Tip
Wall type	Identical	Regular wall
Nozzle type	Identical	Needle and hub are integral to the syringe, not separable.
Barrel marking specs	identical	conforms to ISO 7886-1:1993/ Corrigendum 1:1995
Gradations legibility	identical	0.2ml
Needle cover color	identical	clarity
Lubricant composition	identical	Polydimethylsiloxane oil(PDMS)
Lubricant amount/cm^2	Identical	<0.25mg/cm^2
Barrel transparency	Identical	transparency
Delivery accuracy	Identical	conforms to ISO 7886-1:1993/ Corrigendum 1:1995

Element of comparison	Subject Device	Claimed SE Device
Needle cover strength	Identical	<15N
Hub/needle bond strength	Identical	40N
Biocompatibility	Identical	Conform to 10993-1:2009
Materials	Identical	Plastic parts Polypropylene
		Needle: Stainless Steel
		Needle Hub: PE
		Piston: Rubber
Latex Free	Yes	Yes
Syringe type	Identical	Antistick syringe
Reuse	Identical	Non-reusable
Sterility	Identical	Sterilized by EO; SAL=10^{-6}

Performance Testing:

Biological, sterility and performance testing have been ac complished according to the table below to demonstrate this product is substantially equivalent to the predicate device. The submitted device passed all of these tests.

No	Serial Number/version	Standard and description
1	ISO10993-1:2009	Biological evaluation of medical devices
2	ISO10993-5:2009	Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity.
3	ISO 10993-10:2010	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
4	ISO10993-11:2006	Test for systemic toxicity (Acute)
5	ISO7886-1:1993/ Corrigendum 1:1995	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
6	ISO 7864 T hird edition 1993-05-15	Sterile hypodermic needles for single use.
7	AAMI/ANSI/ISO 10993-7:2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
8	AAMI/ANSI/ISO11607-1:2006/(R)2010	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
9	ISO 11737-1:2006	Sterilization of medical devices-Microbiological methods-Part 1: Determination of the population of microorganisms on
10	ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods -Part 2: Tests of sterility performed in the definition, validation
11	ISO/AAMI/ANSI11135-1 :2007	Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
12	ASTM F 1980-07	Accelerated Aging Test

Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification The Sunwell Biotech Co., Ltd. Auto-Disable Sterile Safety Syringe for Single Use, 5mL is substantially equivalent to the predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sunwell Biotech Company, Limited
C/O IRC
Mr. Charlie Mack
Principal Engineer
77325 Joyce Way
Echo, Oregon 97826

OCT 25 2012

Re: K121637
Trade/Device Name: Auto-Disable Sterile Safety Syringe For Single Use, 5ml
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: October 15, 2012
Received: October 19, 2012

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):
Device Name: Auto-Disable Sterile Safety Syringe For Single Use, 5ml

Indications for Use:

The Auto–Disable Sterile Safety Syringe for Single Use ,5ml, is used to inject fluids into, or withdraw fluids from the body. In addition, the retractable needle of the syringe goes into the barrel after use. It is designed to aid in the prevention of needle stick injuries.

Prescription Use ____x__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC 04/22/2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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